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| 09/970,294 | 10/02/2001 | Gary K. Michelson | 101.0070-02000 | 2538 |

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| EXAMINER |
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PRIDDY, MICHAEL B

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| ART UNIT | PAPER NUMBER |
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3732

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,294

Applicant(s)

MICHELSON, GARY K.

Examiner

Michael B Priddy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-135 and 139-202 is/are pending in the application.
- 4a) Of the above claim(s) 96, 102-108, 112, 113, 116, 117, 158, 165 and 166 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 133-135, 143 and 184-202 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 92, 114, 125, 126, 132, 147, 148, 151, 152, 155, 163, 174, 175, 181 and 182 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims rejected are 91, 93-95, 97-101, 109-111, 115, 118-124, 127-131, 139-142, 144-146, 149, 150, 153, 154, 156, 157, 159-162, 164, 167-173, 176-180 and 183.

DETAILED ACTION

Election/Restrictions

Claims 96, 102-108, 112, 113, 116, 117, 158, 165 and 166 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07/24/2003.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 91, 93-95, 97, 109-111, 115, 119, 121-123, 130, 131, 144-146, 149, 150, 153, 154, 156, 157, 159, 161, 162, 164, 168, 170-172, 179, 180 and 183 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. (U.S. 6,045,554) in view of Greenslade (U.S. 5,088,869). Grooms et al. teaches a screw formed of cortical bone for use in the human body, said screw comprising a leading end, a trailing end opposite said leading end, and a shaft therebetween, said shaft having a mid-longitudinal axis, a length and a thread extending from said shaft along at least a portion of its length; said thread configured to cooperatively engage at least a portion of the screw hole of an implant so as to prevent said screw from linear motion along the mid-longitudinal axis of said shaft in a direction opposite to the direction of insertion when said screw is threaded through a screw hole to attach the implant to a bone portion of

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the human body; said screw being formed substantially of cortical bone of a single thickness ("cortical sections are removed from linear aspects of the femur or from the anterior cortex of the tibia"-- column 4, lines 25&26). As set forth in lines 34-36 of column 3, "the head may have a machined, recessed Allen-wrench, star headed driver, Phillips head or slotted head purchase for torque application." Concerning the limitations of claim 179, it should be noted that Grooms et al. teaches screws of their invention being "placed with a custom socket driver".

Grooms et al. therefore teaches all of the limitations of the present invention except said shaft having a cross section transverse to said mid-longitudinal axis, said shaft having a cross section transverse to said mid-longitudinal axis through said thread having a concavely arcuate portion and a convexedly arcuate portion opposite said concavely arcuate portion, said cross section bisecting a rotation of said thread; said thread having a plurality of turns, a majority of said turns including said concavely arcuate portion; further comprising an enlarged portion proximate said trailing end with a dimension transverse to the mid-longitudinal axis of said shaft greater than said outer diameter of said thread, said enlarged portion configured to prevent said trailing end from passing through the screw hole in the implant; wherein said enlarged portion forms a lip, and said enlarged portion including a concavely arcuate portion in said cross section transverse to the mid-longitudinal axis of said shaft.

Greenslade teaches a thread rolling screw having a shaft 17 with a mid-longitudinal axis, said shaft having a cross section transverse to said mid-longitudinal axis through thread 21b having a concavely arcuate portion 27 and a convexedly

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arcuate portion 25 opposite said concavely arcuate portion 27, said cross section bisecting a rotation of said thread 21b; wherein said thread has a plurality of turns and all of said turns include said concavely arcuate portion (the Examiner selects the three turns having concavely arcuate portions illustrated in Fig. 1 as the plurality of turns and all of these include said concavely arcuate portion); said screw further comprises an enlarged portion proximate said trailing end with a dimension transverse to the mid-longitudinal axis of said shaft greater than said outer diameter of said thread, said enlarged portion configured to prevent said trailing end from passing through the screw hole in the implant wherein said enlarged portion forms a lip (see marked up copy of Fig. 1 in Exhibit B). Recessed areas on the crest of screw threads allow for reduced torque while installing the fastener. It would have been obvious to one of ordinary skill in the art at the time of the present invention to form concavely arcuate portions or relieved areas on the thread of Grooms et al. to reduce the torque required while installing the fastener in the human body.

The combination as taught by Grooms et al. in view of Greensdale teaches all of the limitations said enlarged portion including a concavely arcuate portion in said cross section transverse to the mid-longitudinal axis of said shaft. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the enlarged portion such that it included a concavely arcuate portion in said cross section transverse to the mid-longitudinal axis of said shaft, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find

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obvious for the purpose of providing a forming edge in the heating portion or clamp. In re Dailey and Eilers, 149 USPQ 47 (1966).

The combination taught by Grooms et al. in view of Greenslade teaches all of the structural limitations of the present invention, but is silent as to the method of making. The claimed phrase "said concavely arcuate portion being formed from at least a portion of the medullary canal, said cross section bisecting a rotation of said thread" and "said screw being formed by the process of cutting a strip of cortical bone having a single cortical thickness from the long bone in the direction of the longitudinal axis of the long bone and machining said strip to form a thread; said strip of cortical bone is cut with a trephine having a diameter greater than the cortical thickness of the long bone" is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though the combination of references is silent as to the process used to form the screw, it appears that the product would be the same or similar as that claimed.

Claims 98-101 and 160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. and Greensdale as applied to claims 91 and 154 above, and further in view of Huebner (U.S. 6,030,162). Grooms et al. and Greensdale

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teach all of the limitations of the present invention except said trailing end including a second thread having a different thread pitch than said thread along said shaft; wherein the thread pitch of said second thread is similar to a metal screw pitch and the thread pitch of said thread along said shaft is similar to a wood screw pitch.

Huebner teaches an axial tension screw having a trailing end said trailing end having a second thread 826 having a different thread pitch than said thread 824 along said shaft; wherein the thread pitch of said second thread 826 is similar to a metal screw pitch and the thread pitch of said thread 824 along said shaft is similar to a wood screw pitch. Such a thread configuration allows that "as the screw moves forward, axial compression is generated along the length of the root" which will result in "bone fragments (are) being drawn together". It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the thread of the combination such that the pitch of the thread along the shaft was less than that of the second thread to produce axial compression to draw fragments of bone together. It would also have been obvious to one of ordinary skill in the art at the time of the present invention to form an enlarged portion on the trailing end of the screw of the combination so that "the screw may serve as an anchor to hold down a plate."

Claims 118 and 167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. and Greenslade as applied to claims 91 and 154 above, and further in view of Schenk (U.S. 6,048,344). Grooms et al. and Greenslade teach all of the limitations of the present invention except a tip of said leading end is fluted.

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Schenk teaches a bone screw 60 having flutes 70 at its distal tip to permit the screw to be inserted without pre-drilling or tapping. It would have been obvious to one of ordinary skill in the art at the time of the present invention to provide flutes on the tip of the screw of the combination of Grooms et al. and Greenslade to allow insertion of the screw without pre-drilling or tapping.

Claims 120 and 169 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. as applied to claims 94 and 157 above, and further in view of the following. Grooms et al. discloses the claimed invention except for the cortical bone being obtained from a generally intramembraneously formed cortical bone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the screw of Grooms et al. of cortical bone obtained from a generally intramembraneously formed cortical bone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 124, 127-129, 139-142, 173 and 176-178 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grooms et al. and Greenslade as applied to claims 91, 130 and 154 above, and further in view of Klardie et al. (U.S. 6,048,204). Grooms et al. and Greenslade teach all of the limitations of the present invention except the screw being comprised of hydroxyapatite.

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Klardie et al. teaches a self-tapping screw type dental implant formed of titanium alloys or pure titanium but which may be coated with a material to facilitate healing and/or bone growth. "The outer surfaces of the implant may be coated with hydroxyapatite." (lines 32-34 of column 6) It would have been obvious to one of skill in the art to treat or coat the screw of the combination taught by Grooms et al. and Greenslade with hydroxyapatite to facilitate healing and/or bone growth.

Allowable Subject Matter

Claims 92, 114, 125, 126, 132, 147, 148, 151, 152, 155, 163, 174, 75, 181 and 182 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 133-135, 143 and 184-202 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Fri. 8 a.m. - 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Michael B. Priddy

Michael B. Priddy
October 19, 2004

Kevin Shaver
KEVIN SHAVER
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